



DEPARTMENT OF HEALTH & HUMAN SERVICES

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VIA FEDERAL EXPRESS

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

December 8, 2003

Our Reference: CFN 2953099

Henry H. Cheung, President
Charlie Seafood, Inc.
1550 Bancroft Avenue
San Francisco, California 94124

WARNING LETTER

Dear Mr. Cheung:

We inspected your seafood firm on September 30, 2003 and October 2, 2003. We conducted this inspection to determine your firm's compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123.

We found that your firm has serious HACCP deviations. These deviations caused your Farmed Finfish, specifically Bass, Eel, Mud Fish, Mandarin Fish (Chinese Perch), Yellow Croaker, Threadfin Bream, etc., to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish had been prepared, packed, or held under insanitary conditions, whereby they may have been rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP deviations are as follows:

1. You must have product specifications that are designed to ensure that fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for Farmed Finfish, specifically Bass, Eel, Mud Fish, Mandarin Fish, Yellow Croaker, Threadfin Bream, etc., [REDACTED]
2. You must implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for Farmed Finfish, specifically Bass, Eel, Mud Fish, Mandarin Fish, Yellow Croaker, Threadfin Bream, etc., [REDACTED].

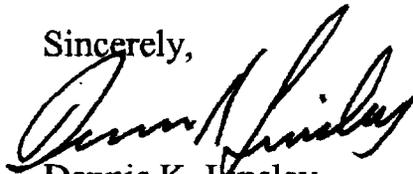
You have had sufficient time to correct the violations. We may initiate regulatory action without further notice if you have not corrected these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may detain your imported seafood products without examination.

The above-identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley

District Director

San Francisco District